

REMARKS

Summary of Office Action

Claims 49, 50 and 53 remain rejected under 35 U.S.C. § 102(b) as allegedly being anticipated by Williams et al., GB 2280111 (hereafter “WILLIAMS”).

Claims 34-57 remain rejected under 35 U.S.C. § 103(a) as allegedly being unpatentable over Guskey et al., U.S. Patent No. 5,776,494 (hereafter “GUSKEY”) in view of Bhakoo et al., US 2003/0059396 A1 (hereafter “BHAKOO”) and Hei et al., U.S. Patent No. 6,593,283 (hereafter “HEI”).

Claims 34-36, 38-45 and 47 remain provisionally rejected on the ground of nonstatutory obviousness-type double patenting as allegedly being unpatentable over claims 46-56 and 64 of copending Application No. 10/574,219.

Claims 34-36 and 38-45 remain provisionally rejected on the ground of nonstatutory obviousness-type double patenting as allegedly being unpatentable over claims 46-48, 54-61 and 63 of copending Application No. 10/574,230.

Claims 34-36, 38-45 and 47 remain provisionally rejected on the ground of nonstatutory obviousness-type double patenting as allegedly being unpatentable over claims 43, 51-53, 56-59, 64, 75 and 81 of copending Application No. 11/586,585.

Response to Office Action

Reconsideration and withdrawal of the rejections of record are again respectfully requested, in view of the following remarks.

Response to Rejection of Claims under 35 U.S.C. § 102(b)

Claims 49, 50 and 53 remain rejected under 35 U.S.C. § 102(b) as allegedly being anticipated by WILLIAMS. The rejection again relies specifically upon Example 9 of WILLIAMS and alleges that this Example discloses a clear gel containing 20% aluminum chlorohydrex (which allegedly is a combination of aluminum chlorohydrate and propylene glycol), 0.5% lactic acid and water. The rejection further alleges that “[s]ince the composition is taught as a gel, the antiperspirant, acid, and water are present in a ratio that resulted in gelling.”

Applicants again respectfully traverse this rejection for all of the reasons which are set forth in the response to the previous Office Action. The corresponding remarks are expressly incorporated herein.

It is pointed out again that the composition of Example 9 of WILLIAMS contains 3 % by weight of the gelling agent dibenzylidene sorbitol. There is no evidence whatsoever that even in the absence of this gelling agent the composition of Example 9 of WILLIAMS would form a gel as well.

Additionally, if the Examiner were correct in assuming that in this composition aluminum chlorohydrate, lactic acid and water are present in ratios which result in gelling, the question would arise why the composition of Example 9 of WILLIAMS contains significant amounts of an (additional) gelling agent (dibenzylidene sorbitol).

In this regard, the following passages of WILLIAMS deserve particular attention (emphasis added):

Clear gel antiperspirant compositions comprise an antiperspirant active, a dihydric alcohol as primary solvent, a cosolvent of polyethylene glycol, water, and/or glycerine, a buffering agent, and a gelling agent. The antiperspirant active is e.g. an aluminium salt or an aluminium and/or zirconium complex. Typical dihydric alcohol components are di or propylene glycol, hexylene glycol and/or pentanediol.

Abstract.

Water can be included in the composition as an alternate or additional cosolvent. Water functions to prevent syneresis or sweating of the composition on exposure to air. In addition, water can also be used to give the composition a dry feel as opposed to a sticky feel. When water is present in the composition, there must be sufficient gelling agent to cause the composition to solidify at a temperature of less than or equal to about 90°C so that the water does not boil off during processing.

The amount of water used should be between about 1% and 20% by weight of the composition. In a preferred embodiment, the amount of water is between about 3% and 15% by weight of the composition; in a more preferred embodiment, the amount of water is between about 5% and 15% by weight; and, in an even more preferred embodiment, the amount of water is between about 5% and 13% by weight.

Page 5, line 25 to page 6, line 8.

A buffering agent or system is used in the composition of the invention to prevent wide pH swings.

Ideally, the buffering agent is an acid/base system having a pK_a of from about 3.5 to about 5, preferably from about 4.5 to about 5.

The buffering agent is selected from phosphate buffers such as sodium or potassium phosphate, phosphoric acid, potassium hydroxide, potassium acid phthalate, triethanolamine, citric acid, sodium citrate, aluminium lactate, lactic acid and mixtures thereof. In a preferred embodiment, a buffer solution of citric acid, sodium citrate and potassium hydroxide is used.

In general, an inorganic buffering agent is more heat stable. However, phosphate buffers, for example, increase the amount of salting or grittiness that occurs on standing due to breakdown of the antiperspirant active salt into insoluble components.

The greater the amount of buffering agent in the composition, the better the stability of the composition and the better the pH is controlled. On the other hand, lower amounts of buffering agents are preferred in order to increase the clarity of the solution and decrease the formation of insoluble components.

The buffering agent is generally present in an amount between about 0.1% and 3% by weight of the composition of the invention. In a preferred embodiment, the buffering agent is present in an amount between about 0.2% and 2% by weight of the composition and in an especially preferred embodiment, the buffering agent is present in an amount between about 0.2% and 1% by weight.

Page 6, line 19 to page 7, line 14.

A material that functions as a gelling agent at a low pH and at high temperatures of up to about 140°C is also present in the composition. The gelling agent is preferably selected from dibenzylidene sorbitol resin, derivatives of dibenzylidene sorbitol resin, and mixtures thereof. In a preferred embodiment, the gelling agent is dibenzylidene sorbitol resin.

In general, dibenzylidene sorbitol resin and its derivatives degrade or decompose under acidic conditions, specifically at a pH of less than about 7, and at high temperatures to form sorbitol and benzaldehyde. This decomposition can be confirmed by the presence of benzaldehyde, which has a characteristic sweet odour that is reminiscent of freshly crushed bitter almonds. However, the presence of the buffering agent in the composition of the invention slows the degradation of the dibenzylidene sorbitol resin considerably, thereby permitting the composition to have little or no almond odour, which is considered acceptable.

The gelling agent is preferably present in an amount between about 1% and 5% by weight of the composition. In a preferred embodiment, the gelling agent is present in an amount between about 2% and 4% of the composition.

Page 7, lines 15-34.

None of the above passages of WILLIAMS provides the slightest indication that in the compositions of WILLIAMS (i) water, if present at all, has a function other than to prevent syneresis or sweating of the composition on exposure to air and to give the composition a dry feel as opposed to a sticky feel, (ii) lactic acid has any function other than to buffer the composition and (iii) the employment of a gelling agent such as dibenzylidene sorbitol is not necessary in order for the composition to form a gel.

Accordingly, the Examiner's allegation that in the composition of Example 9 of WILLIAMS aluminum chlorohydrate, lactic acid and water (necessarily) are present in ratios which result in gelling is nothing more than an unsubstantiated speculation that is not supported by any evidence whatsoever. In this regard, it is pointed out that "the examiner must provide some evidence or scientific reasoning to establish the reasonableness of the examiner's belief that the functional limitation is an inherent characteristic of the prior art" before the burden is shifted to Applicants to disprove the inherency. *Ex parte Skinner*, 2 USPQ2d 1788, 1789 (BPAI 1986). "[T]he statute provides for what may be said to be a presumption of novelty in the language of section 102 'a person shall be entitled to a patent unless ---' (Emphasis added). What this means, in an *ex parte*

proceeding to obtain a patent, is that the Patent Office has the initial burden of coming forward with some sort of evidence tending to disprove novelty.” *In re Wilder*, 429 F.2d 447, 450 (CCPA 1970).

The Examiner also is reminded again that matter is “inherent” if the extrinsic evidence makes it clear that the matter is necessarily present in the thing described in the reference, and that it would be so recognized by persons of ordinary skill. *Titanium Metals Corp. v. Banner*, 778 F.2d 775 (Fed. Cir. 1985); *In re Cruciferous Sprout Litig.*, 301 F.3d 1343, 1349-50 (Fed. Cir. 2002); *In re Crish*, 393 F.3d 1253, 1258-59 (Fed. Cir. 2004). Inherency, however, cannot arise from probabilities or possibilities. The mere fact that a certain thing may result from a given set of circumstances is not sufficient. To the contrary, a certain thing must result from a given set of circumstances to be inherent. *In re Robertson*, 49 USPQ2d 1949, 1950-51 (Fed. Cir. 1999).

Applicants note with appreciation the Examiner’s comments regarding the *cum hoc ergo propter hoc* logical fallacy that Applicants allegedly have engaged in as well as the Examiner’s allegations regarding the philosophical meaning of the phrase “to result in” recited in the instant independent claims. Not having taken any classes in philosophy, Applicant’s representative does not feel in a position to provide any philosophically meaningful counterarguments in response to the Examiner’s allegations. It is submitted, however, that even if one were to assume, *arguendo*, that the use of a gelling agent (dibenzylidene sorbitol) in the composition of Example 9 of WILLIAMS is no indication whatsoever that without this gelling agent the composition would not have formed a gel, the fact remains that the Examiner has failed to provide some evidence or scientific reasoning to establish the reasonableness of the Examiner’s belief that in the composition of Example 9 of WILLIAMS aluminum chlorohydrate, lactic acid and water in fact are present in ratios which would result in gelling even in the absence of a separate gelling agent.

Applicants further point out that the claims of a patent (application) are to be construed as one of ordinary skill in the art would understand them. Applicants are not aware that one of ordinary skill in the art is or can be assumed to have taken classes in philosophy. In this regard, Applicants submit that (possibly in contrast to a philosopher) one of ordinary skill in the art would understand the instant claims to mean that even in the absence of any additional gelling agents components (a), (b) and (c) by themselves must be able to result in (be responsible for, cause, etc.) a gelling of the composition.

It additionally is noted that if the Examiner's construction of the instant claims were correct, i.e., that any ratio of (a), (b) and (c) is considered to result in gelling if the composition is a gel (regardless of the presence or absence of a separate gelling agent), the phrase "(a), (b) and (c) being present in ratios which result in gelling" in the instant independent claims becomes meaningless. Claim language, however, "should not [be] treated as meaningless." *Bicon, Inc. v. Straumann Co.*, 441 F.3d 945, 951 (Fed. Cir. 2006). Claims are construed with an eye toward giving effect to all terms in the claim. *Bicon Inc. v. Straumann Co.*, 441 F.3d 945, 950 (Fed. Cir. 2006). See also *Stumbo v. Eastman Outdoors, Inc.*, 508 F.3d 1358, 1362 (Fed. Cir. 2007) (denouncing claim constructions which render phrases in claims superfluous). Further, "[c]laims are not to be read in a vacuum[;] while it is true they are to be given the broadest reasonable interpretation during prosecution, their terms still have to be given the meaning called for by the specification of which they form a part." *In re Royka*, 490 F.2d 981, 984 (CCPA 1974).

Applicants submit that for at least all of the foregoing reasons and the additional reasons set forth in the response to the previous Office Action, the instant rejection under 35 U.S.C. § 102(b) is without merit and should be withdrawn, which action is again respectfully requested.

Response to Rejection of Claims under 35 U.S.C. § 103(a)

Claims 34-57, i.e., all claims of record, remain rejected under 35 U.S.C. § 103(a) as allegedly being unpatentable over GUSKEY in view of BHAKOO and HEI. The rejection again essentially alleges that GUSKEY teaches a topical pharmaceutical composition comprising at least one active agent, a gelling agent, and an anhydrous solvent and that among the active agents, aluminum and aluminum-zirconium chlorohydrate and mandelic acid are mentioned. The rejection also notes that although GUSKEY teaches that an anhydrous solvent is used, GUSKEY also teaches that the anhydrous solvent may contain up to 5 % of water. The rejection again concedes that “Guskey et al. do not exemplify an embodiment that contains the specific active agents in the claimed ratios” but essentially alleges that this deficiency of GUSKEY is cured by BHAKOO and HEI.

Applicants again respectfully traverse this rejection for all of the reasons which are set forth in the responses to the previous Office Actions and in the Appeal Brief filed March 29, 2010. The corresponding remarks are expressly incorporated herein. See also Applicants’ comments above regarding the alleged philosophical construction of “to result in” adopted by the Examiner in this regard.

Applicants point out again that GUSKEY unambiguously states that the pharmaceutical gel compositions taught therein “preferably contain less than about 5%, preferably less than about 3%, more preferably less than about 1%, most preferably zero percent, by weight of free or added water, other than the water of hydration typically associated with the pharmaceutically acceptable actives prior to formulation”, thereby clearly discouraging the use of water in any amount in the compositions disclosed therein or, at the very least, failing to provide any apparent reason for one of ordinary skill in the art to provide compositions according to GUSKEY which contain more than

insignificant or not reasonably avoidable amounts of water.

In this regard, it is noted that the question here is not even whether GUSKEY discourages, or teaches away from, the use of water in the compositions disclosed therein but rather is whether GUSKEY would have prompted one of ordinary skill in the art to use water in these compositions (e.g., to add water to a substantially anhydrous composition according to GUSKEY). The latter can clearly be answered in the negative, taking into account that according to GUSKEY “the pharmaceutical gel compositions of the present invention preferably contain most preferably zero percent, by weight of free or added water”. Applicants again remind the Examiner that it is necessary for the Examiner to properly construe what an applied reference *fairly* teaches or discloses. See, e.g., *In re Fracalossi and Wajer*, 681 F.2d 792 (CCPA 1982).

It further is pointed out again that the compositions of GUSKEY contain a gelling agent, i.e., an agent whose very purpose is to cause (result in) the formation of a gel, wherefore the question arises what would motivate one of ordinary skill in the art to adjust the ratio of antiperspirant active ingredient, α -hydroxycarboxylic acid and water (assuming, *arguendo*, all of these components can reasonably be expected to be present at the same time in a composition according to GUSKEY) to result in gelling, i.e., to independently form a gel by themselves, in addition to the gel formed by the gelling agent (if possible at all). The Examiner further is reminded that “[i]n rejecting claims under 35 U.S.C. § 103, the examiner bears the initial burden of presenting a *prima facie* case of obviousness. Only if that burden is met, does the burden of coming forward with evidence or argument shift to the applicant.” *In re Rijckaert*, 9 F.3d, 1531, 1532 (Fed. Cir. 1993), citing *In re Fine*, 837 F.2d 1071, 1074, 5 U.S.P.Q.2d 1596, 1598 (Fed. Cir. 1988).

Apart from the fact that for at least all of the reasons set forth above, GUSKEY fails to teach or suggest employing an antiperspirant active agent, an α -hydroxycarboxylic acid and water in ratios which result in gelling of the composition it is not seen that GUSKEY provides an apparent reason for one of ordinary skill in the art to employ mandelic acid and an antiperspirant active such as aluminum or aluminum-zirconium chlorohydrate in combination.

In particular, it is pointed out again that mandelic acid is mentioned in GUSKEY as an example of an exfoliating agent whereas aluminum and aluminum-zirconium chlorohydrates are mentioned in GUSKEY as examples of antiperspirant actives which may be present in the compositions taught therein. It is not seen that one of ordinary skill in the art has an apparent reason to include an antiperspirant active in a composition for exfoliating the skin or to include an exfoliating agent in an antiperspirant composition. After all, someone using an antiperspirant composition on the skin (e.g., in the armpits) does not usually wish the skin to exfoliate there, and neither will someone be interested in an exfoliant having antiperspirant properties. In particular, an antiperspirant is effective only as long as it is present on the skin, whereas an exfoliant is not supposed to stay on the skin but is rinsed off once it has served its purpose, wherefore it would not make sense to add an antiperspirant to an exfoliant (due to its only temporary presence on skin) and may even be harmful (especially to the sensitive skin in the armpits) to add an exfoliant to an antiperspirant composition. In this regard, it is pointed out that the Examiner has failed to provide any evidence which would contradict these statements, and in particular has not provided any evidence whatsoever which could be considered to support an allegation that it is not unusual for antiperspirants to contain exfoliating agents and/or for exfoliating agents to contain antiperspirants.

It further is submitted again that neither of BHAKOO nor HEI are able to cure the noted deficiencies of GUSKEY. In this regard, it is pointed out again that HEI merely teaches antimicrobial compositions which contain antimicrobially active solvents and preferably contain an (optional) additional antimicrobial agent which can be dissolved or dispersed in the antimicrobially-active solvent or in the diluting solvent. Mandelic acid is included in a laundry list of specific compounds and types of compounds of most diverse structures that may be used as (optional) additional antimicrobial agent. Further, none of the numerous exemplified compositions of HEI appears to contain mandelic acid.

Applicants also note again that while HEI discloses a large number and variety of potential uses for the antimicrobial compositions disclosed therein a more than temporary contact of these compositions with human skin is not taught or suggested. The closest disclosure in this regard appears to be in col. 12, lines 28-30 of HEI where the use of the compositions taught therein “for treating skin diseases on animals (especially mammals)” is mentioned.

Applicants note that in this regard the Examiner points to col. 12 of HEI where it is stated that skin diseases include athlete’s foot (a disease that allegedly afflicts (only) humans) and where it is also stated that the compositions of HEI can be used, *inter alia*, as hand soaps and pre-or post-surgical scrubs.

However, it is apparent that hand soaps and pre-or post-surgical scrubs come into contact with human skin only temporarily, i.e., only for very short periods of time, in contrast to an antiperspirant composition according to GUSKEY. Further, athlete’s foot apparently is a condition that can affect animals as well. In particular, HEI states in col. 12, lines 28-41 (emphasis added):

The antimicrobial compositions of the invention can be used for treating skin diseases on animals (especially mammals), or those which spread via transfer to air or surface substrates, such as disease from fungi, molds, bacteria spores and viruses. These spreadable skin diseases include athletes foot fungus and hairy hoof wart disease, and the many organisms leading to Mastitis and other mammalian milking diseases. The disease can be a viral disease such as parvovirus, coxsackie virus, or herpes virus. The disease can also be bacterial, such as S. aureus, E. coli, Streptococci, etc., or a Mycobacterium type such as that leading to tuberculosis. The compositions may also be used to treat animal carcasses to reduce both pathogenic and non-pathogenic microbial levels.

The above passage of HEI leaves no doubt that the “athletes foot fungus” mentioned therein is meant to affect animal skin (just like the “hairy hoof wart disease” mentioned in the same sentence).

Applicants submit that for at least all of the foregoing reasons and the additional reasons set forth in the responses to the previous Office Actions and the Appeal Brief filed March 29, 2010, the rejection of claims 34-57 under 35 U.S.C. § 103(a) over GUSKEY in view of BHAKOO and HEI is without merit as well, warranting withdrawal thereof.

Response to Provisional Rejections of Claims

Claims 34-36, 38-45 and 47 remain provisionally rejected on the ground of nonstatutory obviousness-type double patenting as allegedly being unpatentable over claims 46-56 and 64 of copending Application No. 10/574,219; claims 34-36 and 38-45 remain provisionally rejected on the ground of nonstatutory obviousness-type double patenting as allegedly being unpatentable over claims 46-48, 54-61 and 63 of copending Application No. 10/574,230; and claims 34-36, 38-45 and 47 remain provisionally rejected on the ground of nonstatutory obviousness-type double patenting as allegedly being unpatentable over claims 43, 51-53, 56-59, 64, 75 and 81 of copending Application No. 11/586,585.

Applicants again respectfully request that the above provisional rejections be held in abeyance until the Examiner has indicated allowable subject matter. Applicants will then decide whether the filing of one or more terminal disclaimers is appropriate.

CONCLUSION

In view of the foregoing, it still is believed that all of the claims in this application are in condition for allowance (with the possible exception of obviousness-type double patenting issues). If any issues yet remain which can be resolved by a telephone conference, the Examiner is respectfully invited to contact the undersigned at the telephone number below.

Respectfully submitted
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